

K101062

510(k) Summary  
[As required by 21 CFR 807.92(c)]

1. Submitter's Name / Contact Person

Submitter: TriReme Medical, Inc.  
7060 Koll Center Parkway, Suite 300  
Pleasanton, CA 94566

MAY 12 2010

Contact Person: Shiva Ardakani  
VP of RA/QA  
Phone: 925-931-1300 Ext 209  
Fax: 925-931-1361

Date Prepared: May 4, 2010

2. General Information

Trade Name: GliderXtreme™ PTA Balloon Catheter  
Common/Usual Name: Angioplasty Catheter  
Classification Name: Percutaneous Catheter (21 CFR 870.1250)  
Product Code: DQY / LIT  
510(k) number:

Predicate Devices: NanoCross PTA Dilatation Catheter (K090849)

Sterling ES MR and OTW PTA Balloon Dilatation Catheters  
(K080982)

EverCross .035" OTW PTA Dilatation Catheter (K082579)

3. Intended Use

The GliderXtreme™ PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. NOT for use in the coronary or cerebral vasculature.

4. Device Description

The GliderXtreme™ PTA Balloon Catheter is a standard balloon dilatation catheter with a braided shaft and an atraumatic tapered tip. The device is compatible with commonly used accessories, including standard 0.014" and 0.018" guidewires and 5F introducer sheaths (or 6F guide catheters). Overall catheter length is approximately 135 cm.

The distal end of the catheter has a semi-compliant balloon that expands to known diameters at specific pressures. The balloon is available in multiple sizes and contains one or two radiopaque markers to assist with positioning. The shaft is braid reinforced and has a lubricious hydrophilic coating. The proximal end of the device is a common PTA catheter design of a hypotube connected to a plastic hub and strain relief. The hub is used to inflate the balloon; the luer connector is compatible with standard inflation

devices. A second lumen intended for guidewire use is contained within the catheter. The balloon catheters are available in Rapid Exchange or Over-The-Wire configuration.

The GliderXtreme™ PTA Balloon Catheters are supplied sterile and intended for single use only.

#### 5. Performance Data

Bench testing was performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

The following *in vitro* tests were performed:

- Balloon Rated Burst Pressure
- Balloon Inflation and Deflation
- Balloon Fatigue
- Catheter Body Strength (Bond Strength)
- Torsional Strength
- Catheter Diameter, Balloon Profile and Tip Configuration
- Balloon Compliance
- Trackability, Pushability
- Kink Resistance
- Device Interface Compatibility

#### 6. Substantial Equivalence Comparison and Conclusion

All GliderXtreme™ PTA Balloon Catheters are substantially equivalent to the predicate devices in design, materials, packaging, fundamental scientific technology, manufacturing, sterilization and intended use. Performance testing demonstrated that the GliderXtreme™ PTA Balloon Catheter reliably achieved the desired effect and is safe for its intended use. No new questions of safety or effectiveness were identified during device testing. Therefore, All GliderXtreme™ PTA Balloon Catheters are considered substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

TriReme Medical, Inc.  
c/o Chris Lavanchy  
Primary Reviewer  
CITECH  
5200 Butler Pike  
Plymouth Meeting, PA 19462-1298

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

MAY 12 2010

Re: K101062

Trade/Device Name: Glider PTA Balloon Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous catheter  
Regulatory Class: Class II  
Product Code: LIT, DQY  
Dated: May 10, 2010  
Received: May 11, 2010

Dear Mr. Lavanchy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

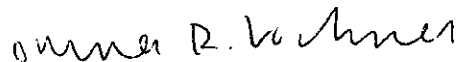
Page 2 – Mr. Chris Lavanchy


forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director, Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (K094019): K101062

Device Name: Glider™ PTA Balloon Catheter

### Indications for Use:

The Glider™ PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.

NOT for use in the coronary or cerebral vasculature.

The indication for use is same for all Glider PTA Balloon Catheter Family.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vc [Signature]  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K101062